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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,845	12/20/2006	Richard L. Friedman	293875US96PCT	1053

22850 7590 11/24/2009
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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11/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/588,845	Applicant(s) FRIEDMAN ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) 6, 42-44, 46-48 and 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 45 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/09/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendments

- 1) Acknowledgment is made of Applicants' preliminary amendments filed 06/11/07, 06/22/09 and 09/21/09.

Election

- 2) Acknowledgment is made of Applicants' election filed 09/21/09 in response to the written lack of unity and/or species election requirement mailed 03/23/09. Applicants have elected invention I, claims 1-5, 45 and 49, and the SEQ ID NO: 5 amino acid sequence species. Because Applicants did not distinctly and specifically point out the supposed errors in the lack of unity, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

- 3) Claims 7-41 have been canceled via the amendment filed 09/21/09.
New claims 42-52 have been added via the amendment filed 09/21/09.
Claims 1-6 and 42-52 are under prosecution.
Claims 6, 42-44, 46-48 and 50-52 are currently withdrawn from consideration as being directed to non-elected species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.
Claims 1-5, 45 and 49 are under examination. A First Action on the Merits has been issued on these claims.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicants' information disclosure statement filed 08/09/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

- 5) Acknowledgment is made of Applicants' sequence listing which has been entered on 02/03/08.

Priority

6) The instant application is a national stage 371 application of PCT/US05/03869, filed 2/09/2005 and claims priority to the provisional applications 60/543,109 filed 02/09/2004 and 60/548,999 filed 03/01/2004.

Objection(s) to Specification

7) The instant specification is objected to for the following reasons:

(a) The use of the trademark in the instant specification has been noted. For example, see pages 12 and 19 for 'Tween 20'; pages 14 and 24 for 'Triton X-100' and 'Coomassie Blue'; page 27 for 'Ficoll Hypaque' and pages 16 and 23 for 'Alexa Fluor'. The trademark recitations should be capitalized wherever they appear and be accompanied by the generic terminology. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar correction to the trademark, wherever it appears.

(b) The disclosure is objected to because it contains an embedded hyperlinks and/or other form of browser-executable codes. See line 7 of page 21 and line 8 of page 5 of the instant specification. Applicants are required to delete the embedded hyperlinks and/or other form of browser-executable codes by deleting the limitation 'http'. See MPEP § 608.01. It is suggested that Applicants examine the whole specification and make necessary deletions of hyperlinks.

(c) Under 'Brief Description of the Drawing Figures' on page 4 of the specification, the recitations 'Figure 1', 'Figure 2' and 'Figure 6' should be replaced with --Figures 1A, 1B and 1C--, --Figures 2A, 2B and 2C--, and --Figures 6A, 6B and 6C-- respectively to represent the three panels of these figures as depicted in the drawings. Analogous criticism and suggestion apply to the limitation 'Figure 7'. All references to these Figures in the specification should be amended to reflect these changes in numbering.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

9) Claims 2-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 2 and 3 are indefinite in the limitations: ‘about 2 to about 7’ and ‘at least about 5 to about 10’ respectively, because it is unclear what range is encompassed in these limitations. Note that the limitation ‘at least’ has no upper limitation. The limitations ‘about’ and ‘at least about’ are relative terms which are not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the claims. Is a range of 2 ± 10 and 7 ± 10 and at least 5 ± 20 and at least 10 ± 20 encompassed within the scope of the limitations ‘about 2 to about 7’ and ‘at least about 5 to about 10’ respectively?

(b) Claim 4 is indefinite because it lacks proper antecedent basis in the limitation: ‘*Mycobacterium tuberculosis*’. Claim 4 depends from claim 1, which already includes the limitation of ‘*Mycobacterium tuberculosis*’. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --said *Mycobacterium tuberculosis*--.

(c) Claim 5 is indefinite and confusing in the limitation: ‘pili of Claim 1, substantially free of cells of *Mycobacterium tuberculosis*’, because it is unclear what is encompassed in the limitation ‘substantially free’. The pili claimed in claim 1 are isolated and purified. Does it mean that the isolated and purified pili claimed in claim 1 encompass pili that are not free of cells of *Mycobacterium tuberculosis*?

Rejection(s) under 35 U.S.C. § 102

10) The following is a quotation of the appropriate paragraph(s) of 35 U.S.C. § 102 that form the basis for the rejection(s) under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) Claims 1-5, 45 and 49 are rejected under 35 U.S.C. § 102(b) as being anticipated by Reed *et al.* (WO 97/09429 A2 – Applicants’ IDS).

The limitation 'about' in claims 2 and 3 is interpreted in this rejection as ± 10 . It is noted that the pili claimed in claims 1-5 lack a structure limit (SEQ ID numbers) and/or molecular weights limit.

Reed *et al.* taught isolated and purified (i.e., substantially free of cells) soluble *Mycobacterium tuberculosis* polypeptide antigens. One such antigen comprises the instantly claimed amino acid sequence of SEQ ID NO 5, i.e., the amino acid sequence having the accession number AAW32374. The antigens are produced by a method wherein *M. tuberculosis* cells are subjected to sonication (i.e., mechanical shearing) and isolating the antigens following centrifugation. See Examples 2-3; pages 9 and 134; and SEQ ID NO: 87, the amino acid sequence of YYWCPG. The prior art polypeptide antigen has the amino acid sequence that is 100% identical in structure with the instantly claimed SEQ ID NO: 5. See the sequence alignment depicted below.

AAW32374

ID AAW32374 standard; protein; 103 AA.
AC AAW32374
DT 15-JUN-2007 (revised)
DT 13-JAN-1998 (first entry)
DE Mycobacterium tuberculosis antigen YYWCPG.
KW Antigen; immunogen; vaccine; tuberculosis; non specific adjuvant;
KW skin testing; M.tuberculosis; BOND_PC; SECRETED PROTEIN ANTIGEN;
KW SECRETED PROTEIN ANTIGEN [Mycobacterium tuberculosis H37Rv];
KW SECRETED PROTEIN ANTIGEN [Mycobacterium bovis AF2122/97];
KW Secreted protein antigen [Mycobacterium bovis BCG str. Pasteur 1173P2]
KW secreted protein antigen [Mycobacterium tuberculosis H37Ra];
KW secreted protein antigen [Mycobacterium tuberculosis C];
KW secreted protein antigen [Mycobacterium tuberculosis str. Haarlem].
OS Mycobacterium tuberculosis.
PN WO9709429-A2.
PD 13-MAR-1997.
PF 30-AUG-1996; 96WO-US014675.
PR 01-SEP-1995; 95US-00523435.
PR 22-SEP-1995; 95US-00532136.
PR 22-MAR-1996; 96US-00620280.
PR 05-JUN-1996; 96US-00658800.
PR 12-JUL-1996; 96US-00680573.
PA (CORI-) CORIXA CORP.
PI Reed SG, Skeiky YAW, Dillon DC, Campos-Neto A, Houghton R;
PI Vedvick TH, Twardzik DR;
DR WPI; 1997-192904/17.
DR N-PSDB; AAT91421.
DR PC:NCBI; gi31620089.
PT New immunogenic polypeptide(s) from soluble M. tuberculosis antigens -
PT useful for diagnosis of M. tuberculosis infection.
PS Example 3; Page 134; 190pp; English.

CC A new immunogenic polypeptide has been developed comprising an
 CC immunogenic part of a soluble Mycobacterium tuberculosis antigen (or its
 CC variant differing only in conservative substitutions and/or
 CC modifications). The present sequence represents a M.tuberculosis
 antigen,
 CC YYWCPG. The immunogenic polypeptide can be used to diagnose
 CC M.tuberculosis infection by forming complexes with specific antibodies
 in
 CC the sample. Fragments of DNA encoding the immunogenic polypeptide can be
 CC used as diagnostic primers or probes and agents that bind to the
 antigen,
 CC especially monoclonal antibodies or equivalent polyclonal antibodies,
 are
 CC also used for diagnosis
 SQ Sequence 103 AA;

Query Match 100.0%; Score 598; DB 1; Length 103;
 Best Local Similarity 100.0%; Pred. No. 8.7e-54;
 Matches 103; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

Qy 1 MYRFACRTLMLAACILATGVAGLGVGAQSAQTAPVPDYYWCPGQPFDPWGPWNWDPYTC 60
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
 Db 1 MYRFACRTLMLAACILATGVAGLGVGAQSAQTAPVPDYYWCPGQPFDPWGPWNWDPYTC 60
 Qy 61 HDDFHRDSDGPDHSRDYPGPVLEGPVLDDPGAAPPPPAAGGGA 103
 ||||||||||||||||||||||||||||||||||||||||||||
 Db 61 HDDFHRDSDGPDHSRDYPGPVLEGPVLDDPGAAPPPPAAGGGA 103

‘Products of identical chemical composition can not have mutually exclusive properties.’ A
 chemical composition and its properties are inseparable. Therefore, if the prior art teaches the
 identical chemical structure, the properties Applicants recite and/or claim are necessarily present.
In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1-5, 45 and 49 are anticipated by Reed *et al.*

Claims Objection(s)

12) Instant claims are objected to for the following reason:

In claims 2-5 and 49, it is suggested that Applicants replace the limitation ‘Claim’ with
 the limitation ‘claim’.

Remarks

13) Claims 1-5, 45 and 49 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile
 transmission. Papers should be transmitted to the Office’s Central Rightfax number 571-273-

8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

November, 2009